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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,903	07/23/2001	Hugh J. Pasika	07414.0025-01000	4264
22852	7590	07/25/2005	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			LY, CHEYNE D	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/911,903		PASIKA ET AL.	
	Examiner		Art Unit	
	Cheyne D. Ly		1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/29/04; 1/12/05; 5/04/05
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8, 19, 20, 29-32 and 34-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-18, 21-28 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed September 29, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The new title and drawings, and the amendment to the specification have been entered.
3. The withdrawal of claims 7, 8, 19, 20, 29-32, and 34-63 has been acknowledged.
4. Claims 1-6, 9-18, 21-28, and 33, nucleic acid, are examined on the merits.

IDS

5. The US Patent No. 6,274,317 B1 and the reference by Jenson H. listed on the IDS, filed September 30, 2004, have been fully considered.
6. The U.S. Application No. 09/724,910, filed November 28, 2000, and related responses and Office Actions have been considered. However, the listed U.S. Application No. 09/724,910, and related responses and Office Actions have been lined through on the IDS, filed September 30, 2004, due to not having a date of publication.

CLAIM REJECTIONS - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-6, 9-18, 21-28, and 33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory algorithm type subject matter.

9. This rejection is maintained with respect to claims 1-6, 9-18, 21-28, and 33, as recited in the previous office action mailed May 18, 2004.

RESPONSE TO ARGUMENTS

10. On page 28, Applicant argues the "Examiner cites no law to support the contention that a physical alteration step outside the system or computer is required for statutory subject matter." Applicant's argument is not persuasive because the instant claims have been rejected under 35 U.S.C. 101 as codified by Congress. Further, the MPEP § 2106 has been cited to provide the basis for the instant rejection.

11. Applicant argues the instant invention "as a whole produces a useful, concrete, and tangible result, the invention is directed to statutory subject matter." Applicant cites *State Street Bank & Trust Co. v. Signature Financial Group Inc.* to support said argument. Applicant's argument and support are not persuasive. *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F. 3d 1368, 1374, 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998) is directed to the "[T]ransformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces a useful, concrete and tangible result' -- a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades." The discussion directed to "a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory

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authorities and in subsequent trades" has been reasonably construed as the controlling of a physical step resulted from said data manipulation. The difference between the claimed invention and the citation above is that the instant claims recite limitations directed to data manipulation without any limitation which could reasonably be construed as controlling any physical steps resulted from said data manipulation.

12. Applicant argues "[i]n the present claims, the allele calling algorithms are used to identify or make an allele call." Applicant's argument is not persuasive because the argued limitations are directed to the manipulation of sequence data using an algorithm without resulting any physical transformation outside of the computing the environment. Regardless of the complexity of the algorithm, the manipulation of sequence using an algorithm has been reasonably construed as a modeling step without resulting any physical transformation outside of the computing the environment.

BASIS FOR REJECTION

13. Claims 1-6, 9-18, 21-28, and 33 are rejected because said claims are directed to a method, system, and computer readable medium comprising steps for inputting and analyzing nucleic acid data without any physical alteration step, which is considered to be non-statutory subject matter. "For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory." (MPEP § 2106 (IV)(B)(2) (b), part ii). Similar to the nonstatutory example above, the instant invention comprises algorithmic steps for inputting and analyzing without any physical alteration resulted from said analysis or modeling steps.

14. It is acknowledged that the instant invention comprises steps for outputting a report, which could reasonably be construed as communication signals between processes that occur entirely within a computer system. However, "such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process" (MPEP § 2106 (IV)(B)(2) (b), part ii).

15. Further, the instant invention comprises a system and computer readable medium with the means for steps for inputting and analyzing nucleic acid data without any physical alteration step outside of said system or computer readable medium resulted for the analysis, which is considered to be non-statutory subject matter.

DOUBLE PATENTING

16. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

17. A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The

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filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

18. The instant rejection has been necessitated by claim amendments.

19. Claims 3, 14, and 25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 34, 38, and 42 of copending Application No. 09/724,910. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

21. Claims 1-3, 9-15, 21-25, and 33 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Allex et al. (September 1999).

22. This rejection is maintained with respect to claims 1-3, 9-15, 21-25, and 33, as recited in the previous office action mailed May 18, 2004.

RESPONSE TO ARGUMENTS

23. On pages 29-30, Applicant argues “Allex uses the term consensus to describe the sequence resulting from the comparison of different individual sequence samples.”

Applicant cites a definition from Lodish et al. to support the above argument and asserts “the consensus calling in Allex refers to a method of determining a consensus sequence and does not suggest using a consensus or more than one calling algorithm to determine such a sequence.” Further, Applicant argues “Allex does not disclose applying at least two different allele calling algorithms to data, and using the results...to make a call and/or assign a confidence level to a call. Applicant’s arguments and cited to support have been fully considered and found to be unpersuasive because Figure 10 (page 728) graphs the accuracy results for the five networks wherein each of the accuracy confidence level is assigned to the networks. For example, the Trace Shape & Intensity network produces the most accurate consensus call as determined from the confidence level of Figure 10 (page 727, column 2, Discussion section). “[T]he best network topology produces consensus accuracies ranging from 99.26% to >99.98% for coverages from two to six aligned sequences (Abstract etc.) which represents the determination of agreement between results of at least two networks (algorithms). Further, the instant specification (page 11) defines “An algorithm is a process of one or more steps for accomplishing a result.” The networks cited above has been reasonably construed to support algorithms as defined by the instant specification wherein each algorithm is an assigned a confidence level.

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24. Therefore, as cited, Alex et al. anticipates every limitation of the argued claims 1, 2, 9-13, 21-24, and 33.

25. Specific to the argued claims 3, 14, and 25 on pages 30-31, Applicant's argument that "Alex does not suggest analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct, and making an allele call for the signal if the threshold test is met. Rather, Alex makes a call irrespective of whether or not the value exceeds a threshold. The threshold is used to determine which call is made, not whether or not a call is made at all." As previously cited, Alex et al. discloses ambiguous calls may also be made by setting a threshold, if more than one output exceeds the threshold, and then the appropriate ambiguous call is made. If only one output is above the threshold, the call is unambiguous (page 726, column 1, lines 4-10). Therefore, the call is determined for outputs exceeding a threshold and no calls are determined for the outputs below said threshold. The citation above anticipates the limitation of "using a computer, analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call. The citation above supports that the method of Alex et al. makes an allele call for the signal when the threshold is met.

26. Further, the limitation of "making an allele call for the signal if the threshold test is met" has been reasonably construed as an optional limitation due to the conditional statement of "if the threshold test is met." The conditional limitation has been reasonably construed as the "making an allele call for the signal" is performed only when "the threshold test is met." Or

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optionally, the “making an allele call for the signal” is not performed when the threshold test is not met. Therefore, a reasonable interpretation of the claimed invention is that the “making an allele call for the signal” is not required when the condition is not met.

27. Applicant further argues “Allex does not discuss an option of not making a call at all based on a failure to meet a threshold test of an allele caller making a correct call.”

Applicant’s argument is not persuasive because the argued limitation is not present in the claims.

28. On pages 32-34, Applicant’s argument directed to claims 4-6, 16-18, and 26-28 has been found to be persuasive. Therefore, claims 4-6, 16-18, and 26-28 have been withdrawn from the instant prior art rejection.

BASIS FOR REJECTION

29. Allex et al. discloses a method of using a system for consensus calling by processing fluorescent trace data (page 723, Abstract etc. and column 2, lines 10-13).

30. The system of Allex et al. accepts fluorescent trace data as inputs (page 724, column 2, lines 2-11) wherein base calls are indicated by total agreement (Figure 1), as in instant claim 1, line 2.

31. The method of Alex et al. comprises five network topologies (Base call, Trace shape,...all (algorithms)) wherein a consensus call with one of these networks has the highest output value, and its corresponding base or gap is the consensus call (agreement). "In the case of heterozygote genomes, ambiguous calls pinpoint differences between alleles (page 725, column 1, line 3, to page 726, column 2, line 4), as in instant claim 1, lines 3-6.

32. The method of Alex et al. comprises five network topologies wherein the algorithms are Base call, Trace shape, Gap Fraction, and Trace Peak Intensities (page 725, column 1, lines 3-18), as in instant claim 2. It is noted that the above algorithms do not have the same nomenclature as those recited in claim 2, however, the cited algorithms serve the same functions as the algorithms disclosed in the instant specification. For example, Alex et al. discloses the Trace Shapes algorithm which takes trace information (from a sequencer) as inputs, computes peak scores for each of the four traces in each sequence; and the scores are weighted by quality (threshold) and averaged (Figure 3, and page 725, column 1, lines 13-16). The algorithm of Alex et al. is directed to heterozygous alleles (page 726, column 2, lines 1-4). The disclosure of Alex et al. above is consistent with the envelope detection caller algorithm of the instant application (page 47) as recited in claim 2.

33. Ambiguous calls may also be made by setting a threshold, if more than one output exceeds the threshold, and then the appropriate ambiguous call is made. If only one output is above the threshold, the call is unambiguous (page 726, column 1, lines 4-10). Therefore, the

call is determined for outputs exceeding a threshold and no calls are determined for the outputs below said threshold, as in instant claim 3.

34. "The example is extracted from fragment assemblies of a 124 kb section of *E. coli*" (page 727, column 1, lines 12-13), as in instant claims 13 and 15.

35. The method of Alex et al. comprises five network topologies (Base call, Trace shape,...all (algorithms)) wherein a consensus call with one of these networks has the highest output value (high level of confidence), and its corresponding base or gap is the consensus call (agreement). "In the case of heterozygote genomes, ambiguous calls pinpoint differences between alleles" (page 725, column 1, line 3, to page 726, column 2, line 4).

Figure 8 illustrates the different strategies for each of the respective algorithms cited above, as in instant claim 9, lines 1-9, claim 10, claim 12, claim 21, lines 5-11, and claim 22.

36. Ambiguous calls may also be made by setting a threshold, if more than one output exceeds the threshold, then the appropriate ambiguous call is made. If only one output is above threshold, the call is unambiguous (levels of confidence) (page 726, column 1, lines 4-10). Base calls that have been erroneously inserted, the consensus show as gap, meaning no base exists (Figure 1), as in instant claim 9, lines 10-13, claim 21, lines 12-15, and claim 25.

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37. A report captures data generated from the above algorithms which reflects the accuracy of base calls (page 727, column 2, Discussion §, lines 6-11, and Figure 10), as instant claim 9, lines 14-15, and claim 21, lines 16-17.

38. The system of Alex et al. accepts data from DNASTAR's SeqMan II (page 727, column 1, lines 12-16). The inclusion a document by Jensen HB is not being used as prior art, but, only to show the inherent characteristic of DNASTAR. Jensen HB discloses DNASTAR is a program that runs on an IBM personal computer (processor and memory) (Jensen HB, Abstract etc.), as in instant claim 11, claim 14, claim 21, lines 1-4, claim 23, lines 1-3, and claim 33, lines 1-2.

39. Further, the system of Alex et al. accepts fluorescent trace data as inputs (page 724, column 2, lines 2-11) wherein base calls are indicated by total agreement (Figure 1), as in instant claims 11 and 14.

40. The method of Alex et al. comprises five network topologies (Base call, Trace shape,...all (algorithms)) wherein a consensus call with one of these networks has the highest output value (confidence level), and its corresponding base or gap is the consensus call (agreement). "In the case of heterozygote genomes, ambiguous calls pinpoint differences between alleles (page 725, column 1, line 3, to page 726, column 2, line 4), as in instant claim 11, lines 5-8, claim 14, lines 5-6, claim 23, lines 4-7, claim 24, and claim 33, lines 3-6.

CONCLUSION

41. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

42. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

43. This application contains claims 7, 8, 19, 20, 29-32, and 34-63 drawn to an invention nonelected, January 30, 2004. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

44. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.

45. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free


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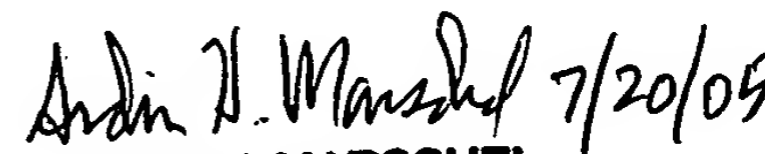
number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

46. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

47. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly 
7/19/05

 7/20/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER